Receipt date: 11/19/2010

Examiner

Signature

PTO/SB/08a (09-08) Approved for use through 10/31/2008 OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Beduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | Un | der the Pape | erwork F | Reduction Act of | 1995, no pers | ons are requ | ired to respo | ond to a collection | n of inform | ation unless it contains a valid Of | MB control nur | |
|-----------------------------------|--------------|--|--------------|---------------------------------|--|---|---------------------------|---------------------------------|---|---|----------------|--|
| Substitute for form 1449A/PTO | | | | | | Complete if Known | | | |) | | |
| INFORMATION DISCLOSURE | | | | | | Application Number | | 10/528,577 | | | | |
| | | | | | | Filing Date | | | March 21, 2005 | | | |
| STATEMENT BY APPLICANT | | | | | First Named Inventor | | Ulrich SPECK et al. | | | | | |
| STATE DAN | | | | | | Art Un | it | | 3763 | | | |
| (Use as many sheets as necessary) | | | | | | | ner Name | | Laura | A. Bouchelle | | |
| Sheet | 1 | | of | 3 | | Attorn | ey Docket | Number | WEI | WEICKM-0044 | | |
| | • | | | | U.S. PA | TENT C | ОСИМЕ | NTS | | | | |
| | | Document Number | | Number | Dallad | an Data | | Patentee or App | licant of Bases Columns Luces Where | | - Belowest | |
| Examiner Initials * | Oite No | Number - Kind Code ² (if known) | | | Publication Date MM-DD-YYYY | | Cited Document | | Pages, Columns, Lines, Where Releva Passages or Relevant Figures Appear | | | |
| | A1 | 4.502,159 | | 03-05-85 | | Woodroof et al. | | | | | | |
| | A2 | 4,950,25 | | | | 08-21-1990 | | Luther et al. | | | | |
| | A3 A4 | 6,264,62 | | | | -24-2011 Desmond -09-2002 Palasis et | | | | | | |
| | A5 | 6,369,03 | | | | | | | | | | |
| | A6 | 7.611.53 | | | | 07-16-2002 11-03-2009 | | Yang et al. Bates et al. | | | | |
| | A7 | | 7,611,532 | | _ | 07-06-2010 | | Speck et al. | | | | |
| | A8 | 7,811,622 | | 10-12-2010 | | Bates et al. | | | | | | |
| | A9 | 2007/012 | 2007/0128118 | | | 3-07-2007 Yu et al. | | | | | | |
| | | | | | FORE | IGN PA | TENT D | OCUMENT | s | | | |
| Formation of | 011- | Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | name of Patentee or Applicant of Cited Document | | Pages, Columns, Lines, | | | | |
| Examiner Initials* | Cite No.1 | | | | Code ⁶ (if Publicati MM-DD | | | f Cited | Where Relevant Passages or Relevant Figures Appear | T ⁶ | | |
| | B1 | DE 44 35 652 | | | 04-11- | | Stembe | rger | | C24 | | |
| | B2 | DE 195 14 104 | | | 11-28-19 | | Haft | | | C25 | | |
| | B3 | DE 69925936 | | | 06-08- | | Palasis et al. | | | C26 | | |
| | B4 | EP 0 551 182 | | | | 07-14-1993 | | Morris et al. | | | C27 | |
| | B5 | WO 96/20718 | | | | 07-11-1996 Hart e | | | | | | |
| | B6 | | WO 96/25282 | | | | -1996 | Kaulmann | et al. | | C28 | |
| | | | | | ON PATEN | T LITERA | TURE DOC | UMENTS | | | | |
| Examiner Initials * | No.1 | | | ook, magazi | ine, journal | , serial, s | mposium | | c.), date | nen appropriate), title of , page(s), volume-issue hed. | T 2 | |
| | C1 | BAUME Transfe pp. 102 | rs into | T AL., "Local the Arterial W | Drug Deliver all," Catheriz | ry: Impact of ration and | of Preassur Cardiovasc | re, Substance ular Intervention | Characte ons, Wile | ristics and Stenting on Drug y-Liss, Inc., 1999, Vol. 47, | | |
| | C2 | Series | of extra | cts from the L | JK Trademar | ks Registe | r, April 29, | 2008 | | | | |
| | СЗ | IUPAC, | Comp | endium of Ch | emical Termi | inology (19 | 87) | | | | | |
| | C4 | Table of General Chemical Information, October 12, 2009 | | | | | | | | | | |

*EXAMINER. Initial if reference considered, whether or not citation is in conformance with MPEP 609, Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached

Date

Considered

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete. including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Receipt date: 11/19/2010

Substitute for form 1449A/PTO

C18

Examiner

Signature

PTO/SE/08a (09-08)
Approved for use through 10/31/2008 OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Complete if Known

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | Application Number 10/528,577 | | | |
|-----------------------------------|--------------|---|---------|---|--------------------------------------|---|---|--|
| INFORMATION DISCLOSURE | | | | | Filing Date March 21, 2005 | | | |
| STAT | EME | NT BY A | ŀΡΕ | PLICANT | First Named Inventor | Ulrich SPECK et al. | | |
| | | | | | Art Unit 3763 | | | |
| (Use as many sheets as necessary) | | | | | Examiner Name | Laura A. Bouchelle | | |
| Sheet | 2 | of 3 | | | Attorney Docket Number | WEICKM-0044 | | |
| | | | | NON PATENT | LITERATURE DOCUMENTS | | | |
| Examiner Initials * | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | | | | |
| | C5 | Product information DIOR balloon catheter of Eurocor GmbH, October 1, 2008 | | | | | | |
| | C6 | KALBITZ et | al., *f | Modulation der Wirkstoff | penetration in die Haut," Pharma. | zie, 1996, Vol. 51, pp. 619-637 | _ | |
| | C7 | | | SIGNY et al., "Local Deliv c. Interv. Radiol., 1994, V | | rith use of hydrogel-coated angioplasty | | |
| | C8 | DRACHMANN et al., "Neoinitimal thickening after stent delivery of pacitiaxel: Charge in composition and arrest of growth over six month," J. Am. Coll. Cardiol., 2000, Vol. 36, pp. 2325-2332 | | | | | | |
| | C9 | Abstracts Fr | om tř | ne 70 th Scientific Session | s, Circulation, October 21, 1997, | , 96 Suppl. 1: 1-288 | | |
| | C10 | VAN BELLE | E E | T Al "Descivation of m | atallic etante after arterial cana t | ranelar of phVEGE165 inhibite thrombus | _ | |

formation and intimal thickening," J. Am. Coll. Cardiol., 1997, Vol. 29, pp. 1371-1379

Wersuchsheechreibungen (DAM) ("Description of experiments"). July 9, 2010.

Affidavit (D46), July 9, 2010

Final Report Study ACL435-43 (D47), May 14, 2009

Summary Data Biotronik SE & Co. KG (D49), July 9, 2010

Submission BpatG (Ceramide Balloon Catheter) MLA HLA (D49), July 9, 2010

German Translation of "Gericht zu's Gravenhage, 245382/HA ZA 05-2016 (D49A)

Press release of 17 January 2007 repairding patent infringement suit (D49C)

MORTIMER, C. ET AL., Basiswissen Chemie (excerpt) (1987) (D50)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw fine through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
*Applicant's unjugic extraor designation number (opinion). *Applicant is unjugic extraor let English language Translation is attached.

Date

Considered

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to life (and by the USPTO be process) an application. Colliderality is governed by \$8 U.S. O. 12 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete including spatienting, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case Any committee or the amount of time pay in expense to complete the form and/or suggestions for reducing this butter, should be sent to the CFR of the formation of the committee of the submitted of the sent to the CFR of the formation of the committee of the contract of the committee of the committe

Receipt date: 11/19/2010

Substitute for form 1449A/PTO

C24

C25

COR

Examiner

Signature

PTO/SB/08a. (09-08)
Approved for use through 10/31/2008 OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Complete if Known

12/02/2010

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | Application Number | 10/528,577 | | | | |
|------------------------|--------------|---|---|--|--------------------|--|--|--|--|
| INFO | RMAT | TION DIS | CLOSURE | Filing Date March 21, 2005 | | | | | |
| STAT | EME | NT BY A | PPLICANT | First Named Inventor Ulrich SPECK et al. | | | | | |
| | | | | Art Unit | 3763 | | | | |
| | (Use as r | nany sheets a: | necessary) | Examiner Name | Laura A. Bouchelle | | | | |
| Sheet | 3 of 3 | | | Attorney Docket Number | WEICKM-0044 | | | | |
| | | | NON PATENT | LITERATURE DOCUMENTS | | | | | |
| Examiner Initials * | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where publisher. | | | | | | | |
| | C19 | Summons to attend Oral Proceedings dated June 4, 2010 (D51) | | | | | | | |
| | G20 | GERSHLICK ET AL., "Inhibition of Restenosis with a Pacitaxel-Eluting, Polymer-Free Coronary Stent: The European evaluation of pacilTaxel Eluting Stent (ELUTES) Trail," Circulation, 2004, Vol. 109, pp. 487-493 | | | | | | | |
| | C21 | | INDOLFI ET AL., "Smooth Muscle Cell Profiferation Is Proportional to the Degree of Balloon Injury in a Rat Model of Angioplasty," Circulation, 1995, Vol. 92, pp. 1230-1235 | | | | | | |
| | C22 | MANDERSON ET AL., "Balloon Catheter Injury to Rabbit Cartoid Artery. I. Changes in smooth muscle phenotype," Artheriosklerosis, 1989, Vol. 9, pp. 289 | | | | | | | |

STEMBERGER, AXEL DR., "Coating for bio-material to be used e.g. as sutures," Retrieved from Espacenet on

STEMBERGER, AXEL, DR., "Coating for bio-material insertable into the bloodstream or tissue of the human body." Retrieved from Espacenet on November 19, 2010; English Abstract of DE 19514104

STEMBERGER, AXEL, DR., High efficiency local drug delivery.* Retrieved from Espacenet on November 19, 2010; English Abstract OE 809625936

MORRIS, R. E. ET AL., "Method of treating hyperproliferative vascular disease using rapamycin, eventually in combination with mycophenolic acid." Retrieved from Espacenet on November 19, 2010; English Abstract of EP0551182

KAUFHANN G. ET AL., "Process for producing a plastic clading component and clading component produce specially by said process." Retrieved from Espacenet on November 19, 2010; English Abstract of WOS625828

Date

Considered

Data Supplement to R. Charles et al., Circulation Research, 2000, Vol. 87, pp. 282

November 19, 2010; English Abstract of DE 4435652

/Laura Bouchelle/

| *EXAMINER: Initial if reference considered, whether or not citation is in co- | formance with MPEP 609. Draw line through citation if not in conformance and |
|---|--|
| not considered look do constal this form with next communication to and | |

Applicant's unique chation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CPR 11 a The information is required to obtain or retain a benefit by the public which is to life and by the USPTO to process) an application. Confidentiality is governed by 51 U.S. C. 122 and 37 CPR 1.14. This collection is estimated to take 2 hours to complete deplication from the USPTO Time will vary depending upon the individual case. Any comments on the amount of time you require to complete his form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patentian of Translation (Gife. U.S. Department of Commence, PC). Box 1450, Maxandria, VA 22313-445, D. DNOT SENDESS OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, cell 1-800-PTO-9199 and select option 2.